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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,685	11/07/2001	Kurt E. Petersen	22660-0019 DIV 2	1753

7590

11/06/2002

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-9

Office Action Summary	Application N .	Applicant(s)	
	10/005,685	PETERSEN ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002 and 19 July 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 O.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-226 is/are pending in the application.
- 4a) Of the above claim(s) 137-214 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-56, 58-60, 62-82, 84-100, 102-118, 120-127, 129-136 and 215-226 is/are rejected.
- 7) ☒ Claim(s) 57, 61, 83, 101, 119 and 128 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 137-214 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 54-136 and 215-226, drawn to a method for separation of an analyte from a sample liquid which includes mechanical cell lysis and analyte extraction, classified in class 436, subclass 177.
 - II. Claims 137-214, drawn to a method for extraction of nucleic acid from a sample including cells which includes chemical lysis with a paper or membrane material impregnated with chemical agents, classified in class 536, subclass 25.41.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions of Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the mechanical lysing chamber and separate extraction chamber of the claims of Group I is not required of the claims of Group II. The paper or membrane with impregnated chemicals for cell lysing of the claims of Group II is not required of the claims of Group I. None of the claims as presently written link together the inventions set forth in Groups I and II. As a result, the inventions of Group I and Group II are deemed to be independent inventions for the reasons set forth above.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 137-214 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

6. The Information disclosure statement filed 29 April 2002 has been considered and made of record.

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

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The instant declaration only provides the RESIDENCE of each inventor. There is nothing in the declaration to indicate that the residence is also the inventor's post office address.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 54-56, 58-60, 62-63, 68, 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al.(US 6,168,948).

The reference of Anderson et al. discloses a nucleic acid purification method which includes a cell lysing region, a nucleic acid capture region, a reaction chamber (connected or coupled to the other chambers), a detection chamber and a reagent chamber connected to the reaction chamber (See column 6, line 44 to column 12, line 45). With respect to the solid phase binding within the lysing region, the reference discloses the use of posts (1908) and binding reagents (1912). With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28). The reference discloses the use of a reagent chamber prior to amplifying the purified nucleic acids (See column 10, lines 34-39).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 64-67 and 73-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948).

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The reference of Anderson et al. has been discussed above.

With respect to the lysing chamber limitations of claims 64-67, the use of a filter member in place of support posts (1908) for supporting binding reagents (1912) would have been obvious for the known and expected result of providing an alternative means recognized in the art to provide increased surface area for supporting the cell binding agents (1912) in the lysing chamber.

With respect to the presence of a lysing buffer, it would have been obvious to one of ordinary skill in the art to provide reagents and/or buffers which are proper for creating the proper environment for cell lysing while maintaining the viability of the sample and efficiency of the system.

With respect to the use of an ultrasonic horn, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum transducer to employ so as to create the proper ultrasonic energy required for efficient cell lysis.

With respect to the claimed volumes of sample and elution liquid relative to the lysis chamber and/or extraction chamber, in the absence of a showing of criticality and/or unexpected results, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed.

14. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Brunner et al.(US 5,777,141).

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The reference of Anderson et al. has been discussed above.

Claim 72 differs by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

15. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The reference of Anderson et al. has been discussed above.

The above claim differs by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of

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enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

16. Claims 71 and 215-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(6,168,948) in view of Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The reference of Anderson et al. has been discussed above.

While the reference of Anderson et al. discloses a multitude of binding structures (See column 7, lines 24-52) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Anderson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

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In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

17. Claims 81, 82, 84, 86-96, 99, 100, 102-114, 117, 118, 120-124, 126, 127, 130-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029).

The reference of Anderson et al. has been discussed above.

While the reference of Anderson et al. discloses a method of extracting and detecting a nucleic acid sample, the instant claims differ by reciting that the capture region includes a first flow path connected to a waste chamber and a second flow path for eluting the captured sample to a reaction chamber.

The reference of Nelson et al. discloses a cartridge (50) and method of use which includes a sample port (66); a sample flow path (66-62); a flow-through component (62); a waste chamber (63); an elution flow path (57-62-55); and flow controller (58-61) for directing the flow of liquid within the cartridge.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the device of the primary reference of Anderson et al. to include a capture region as suggested by the reference of Nelson et al. for the known and expected result of providing an enrichment region which improves detection efficiency by concentrating analyte from a liquid

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sample and/or removing interfering sample components (See column 3, line 56 to column 4, line 12).

With respect to the volumes of sample relative to the volume of the capture chamber, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

With respect to the lysing chamber limitations of claims 64-67, the use of a filter member in place of support posts (1908) for supporting binding reagents (1912) would have been obvious for the known and expected result of providing an alternative means recognized in the art to provide increased surface area for supporting the cell binding agents (1912) in the lysing chamber.

With respect to the presence of a lysing buffer, it would have been obvious to one of ordinary skill in the art to provide reagents and/or buffers which are proper for creating the proper environment for cell lysing while maintaining the viability of the sample and efficiency of the system.

With respect to the use of an ultrasonic horn, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to

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determine the optimum transducer to employ so as to create the proper ultrasonic energy required for efficient cell lysis.

With respect to the claimed volumes of sample and elution liquid relative to the lysis chamber and/or extraction chamber, in the absence of a showing of criticality and/or unexpected results, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed.

18. Claims 98, 116 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Brunner et al.(US 5,777,141).

The combination of the references of Anderson et al. and Nelson et al. has been discussed above.

The above claims differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

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19. Claims 98, 116 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029), Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Anderson et al. and Nelson et al. has been discussed above.

The above claim differs by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

20. Claims 97, 115, 125 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(6,168,948) in view of Nelson et al.(US 5,770,029), Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the references of Anderson et al. and Nelson et al. has been discussed above.

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While the references of Anderson et al. and Nelson et al. disclose a multitude of binding structures (See column 7, lines 24-52 of Anderson et al. and column 4, lines 24 to column 5, line 38 of Nelson et al.) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Anderson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

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21. Claims 54-56, 59, 56, 68-70, 73-82, 85, 90-96, 99, 100, 103, 108-114, 117, 118, 121-124, 126, 127 and 130-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880).

The reference of Nelson et al. discloses a cartridge (50) and method of use which includes a sample port (66); a sample flow path (66-62); a flow-through component (62); a waste chamber (63); an elution flow path (57-62-55); and flow controller (58-61) for directing the flow of liquid within the cartridge. The device includes a detection chamber (65).

The claims differ by reciting that the device includes a lysing chamber and associated components for releasing nucleic acid from cell samples and the use of a nucleic acid reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microchip device with cell lysing components and nucleic acid reaction and detection components (connected or coupled to the other chambers, See the entire disclosure). The reference also discloses the use of cell binding moieties in a lysing region of the device (See column 13, lines 6-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of Nelson et al. with the additional lysing components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

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With respect to the claimed reagents and reaction chambers and analysis chambers for nucleic acid, the reference of Wilding et al. also discloses these features for detection of nucleic acid samples (See Figures 11A and 11B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference with reagent chamber, reaction chamber, detection chambers, etc. for the known and expected result of providing a device which is capable of extracting and detecting nucleic acid samples as is suggested by the prior art references.

With respect to the volumes of sample relative to the volume of the capture chamber, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

22. Claims 72, 98, 116 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880) and Brunner et al.(US 5,777,141).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

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The above claims differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

23. Claims 72, 98, 116 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of

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enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

24. Claims 71, 97, 115, 125, 135, 215-217, 219, 220 and 223-226 rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

While the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Nelson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

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With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. ⁵⁴
Claims ~~X~~ 56, 58-60, 62-82, 84-100, 102-118, 120-127, 129-136 and 215-226 are
^
provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 and 103-107 of copending Application No. 09/513,443 in view of Anderson et al.(US 6,168,948) or Wilding et al.(US 5,726,026 or 5,928,880).

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Claims 18-22 and 103-107 of the claims of Application '443 encompass a method of separating an analyte from a fluid sample that includes an extraction region and sample volume limitations similar to the claims of the instant application.

The instant claims differ by reciting additional method steps and associated structure with respect to lysing the sample and reacting the analyte separated in the extraction region.

The references of Anderson et al. and Wilding et al. both disclose that it is known in the art to include cell lysing steps and structures for preparing a liquid sample for analyte extraction and the use of reaction steps and detecting steps for analyzing the extracted analyte (nucleic acid) (See the discussions of these references previous of record).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '443 with the additional lysing and reaction steps and components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

This is a provisional obviousness-type double patenting rejection.

27. Claims 54-56, 58-60, 62-70, 73-82, 84-96, 99-100, 102-114, 117, 118, 120-124, 126, 127 and 129-134 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948).

Art Unit: 1744

Claims 1-13 of application '590 encompass a lysing method and associated structure for releasing an analyte from a liquid sample.

The above claims differ by reciting additional method steps which include analyte extraction of the lysed sample and reaction and detection of the extracted sample.

The reference of Nelson et al. discloses a method for extracting an analyte from a liquid sample which includes an extraction region for capturing and eluting a desired analyte (See discussions of Nelson et al. above).

The references of Wilding et al. and Anderson et al. disclose that it is known in the art to provide a microchip device with cell lysing components and reaction and detection components (See the entire disclosure and discussion of these references above).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '590 with the additional lysing components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

With respect to the claimed reagents and reaction chambers and analysis chambers for nucleic acid, the references of Wilding et al. and Anderson et al. also discloses these features for detection of nucleic acid samples (See Figures 11A and 11B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the system of application '590 with reagent chamber, reaction chamber, detection chambers, etc. for the known and expected result of providing a device which is capable of extracting and detecting nucleic acid samples as is suggested by the prior art references.

This is a provisional obviousness-type double patenting rejection.

28. Claims 71, 97, 115, 125, 135 and 215-226 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

While the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Nelson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

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With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

This is a provisional obviousness-type double patenting rejection.

29. Claims 72, 98, 116 and 136 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Brunner et al.(US 5,777,141).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in the device to improve elution efficiency.

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The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

30.

This is a provisional obviousness-type double patenting rejection

31. Claims 72, 98, 116 and 136 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

This is a provisional obviousness-type double patenting rejection

In view of the large number of related applications and numerous sets of claims in these applications, applicants are encouraged to make the Examiner aware of any related applications which do not directly depend from this and/or ensure that these applications do not include conflicting subject matter.

Allowable Subject Matter

32. Claims 57, 61, 83, 101, 119 and 128 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

33. The following is a statement of reasons for the indication of allowable subject matter:

While the prior art of record discloses the use of reactions chambers which are incorporated into or coupled to the channel/chamber systems, the prior art of record fails to teach

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or fairly suggest 1) a reaction chamber incorporated into the channel/chamber cartridge which protrudes from the rest of the cartridge and is inserted into a thermal sleeve for heating or cooling control; 2) a reaction vessel coupled to the cartridge such that the reaction vessel can be inserted into a thermal sleeve for heating or cooling control.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
November 4, 2002